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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,028	12/04/2000	Shiguang Yu	6560	4708

23909 7590 06/13/2003

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EXAMINER
OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
1614	13

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/729,028	Applicant(s) YU ET AL.	
	Examiner Clinton Ostrup	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/6/03*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 15-25 are pending in this application.

Response to Applicant's Amendment

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15-25 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instantly claimed subject matter lacks utility because it is frivolous and the claims appear to have an incredible utility.

First, reading the claims as broadly as possible, the instantly claimed subject matter reads on the natural re-growth of dog and cat hair. The fact that alcohol is applied to the skin of the dog or cat does not change the fact that the hair of the dog or cat would have grown back, naturally. However, applicant does not show a method of applying alcohol alone to the skin of a dog or cat. The only working example in the instant application has at least three method steps: 1) tape stripping, 2) application of alcohol and, 3) application of Panalog cream.

Secondly, there have been very few compounds that have been actually been shown to grow hair (i.e. minoxidil) and applicants claims to a method of the absolute growing hair, by simply applying alcohol to the skin of a dog or cat, is an incredible utility.

Applicant's claims have been amended from accelerating the growth of hair on a dog or cat having alopecia to the absolute growing of hair on a cat or dog or cat having alopecia. None of the working examples show alcohol applied alone, to the skin of a cat or dog as causing hair to grow, but even if they did, it appears that the hair on said dog or cat would have grown back naturally. Therefore, applicant's claims read on a product of nature (i.e. a method of growing hair on a canine or feline), as the hair would grow with or without the method steps claimed instantly.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the rate of hair growth on Beagles by:

1) tape stripping an area of skin 36 times;

2) topically applying, on two separate occasions, two milliliters of a mixture of alcohols comprising 90% ethyl alcohol, 5% methyl alcohol, and 5% isopropanol to the area of skin that has previously been tape stripped; and

3) applying a composition comprising nystatin, neomycin sulfate, thiostrepton and triamcinolone acetonide;

wherein said increase in hair growth rate is greater than the hair growth rate when an area of skin is tape stripped, alone;

or, said increase in hair growth rate is greater than the hair growth rate when a composition comprising nystatin, neomycin sulfate, thiostrepton and triamcinolone acetonide is applied to an area of skin, alone.

However, it does not reasonably provide enablement for the absolute growth of hair, on the skin of a canine of feline having alopecia, by the simple application of the claimed alcohols, without any other method steps. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In fact, applicant has not shown the application of alcohol alone as causing the growth of hair. Applicant has one working example wherein multiple method steps are involved. Applicant compares this method to a method of tape-stripping alone and the application of Panalog cream alone; however, there is comparison of the application of alcohol alone.

Moreover, the method as claimed reads on the natural re-growth of hair on cats and dogs. This process would occur whether the method steps claimed were practiced or not (i.e. even if alcohol was not applied to the skin of the dog or cat).

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention

The nature of the invention relates to a method of growing hair on dogs and cats, by the simple application of commonly used alcohols.

2. The state of the prior art

Kuwana et al., 5,674,497 represents a standard publication in the art and as such is directed to those having ordinary skill in the art.

3. The relative skill of those in the art

The relative skill of those in the art is generally that of a PHD candidate or PHD.

4. The predictability of the art

Kuwana et al demonstrates the unpredictability of the claimed subject matter. Kuwana et al., state that various hair dressing and hair tonics have been used to treat alopecia, however, no medicine having an exact effect has been developed. Moreover, Kuwana et al., use ethanol as a control and compare it to compositions comprising various ethanol extracts of plants, thus demonstrating that alcohol is not a predicted hair-growing compound.

Given the above facts, it is clear that the art to which the instant invention relates, a method of growing hair on dogs and cats, involves a relatively high degree of unpredictability.

5. The breadth of the claims

The claims are very broad and inclusive of any and all methods of growing hair on dogs and cats by simply applying alcohols to the skin of said dogs and cats.

6. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining which particular methods of administering alcohols, known or to be discovered, can reasonably be expected, *a priori*, to exhibit the requisite hair growing effects. Only a limited selection of specified methods are enumerated by the specification, and the working examples are even more limited. In fact, applicant has not shown any working examples where alcohol was solely applied to the skin of a dog or cat. The only demonstration that applicant has shown involves tape stripping, applying alcohol twice, and the application of an additional composition to achieve the increase in the rate of hair growth, as compared to the hair growth rate of tape stripping or the application of Panalog, alone.

7. The quantity of experimentation necessary

Applicant fails to provide guidance and information sufficient to allow the skilled artisan to ascertain what amount of hair growth can be achieved, with or without the application of alcohols. The skilled artisan would expect the hair of a dog or cat to grow back naturally. Absent a clear teaching and showing that the simple application of alcohol to the skin of a dog or cat, by any method, would result in the absolute growth of hair, and an understanding of the biochemical basis for such hair growth, the instant specification sets forth no such understanding nor any criteria for extrapolating beyond those actually demonstrated in Example 1 using a combination of alcohols, tape stripping, and Panalog cream.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered

indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 23 recites the broad recitation of many different alcohols, and the claim also recites the alcohol as being the specific alcohol, ethanol, which is the narrower statement of the range/limitation.

Response to Applicant's Arguments/Amendment

Applicant's arguments filed February 6, 2003, Paper No. 12, to the rejection of claims 15-16 and 21under 35 U.S.C. 102(b) as being anticipated by Luo H1480 have been fully considered. However, they have not been found convincing; therefore, the said rejection has been MAINTAINED.

Applicant argues that the 35 USC 102, anticipation rejection has been overcome by limiting the term alcohol in all the claims. However, Luo teaches compositions comprising ethanol as hair growth compositions. Therefore, applicants' amendment has not made the said rejection moot.

Applicant's arguments filed February 6, 2003, Paper No. 12, to the rejection of claims 15-17, 20-22, and 24 under 35 U.S.C. 103(a) as being unpatentable over Luo H1480 and further in view of The Merck Veterinary Manual, A Handbook of Diagnosis and Therapy for the Veterinarian (Merck) have been fully considered. However, they have not been found convincing; therefore, the said rejection has been MAINTAINED.

Applicant argue that the complex organic material of Luo has nothing to do with the simple aliphatic alcohols presently claimed and the resorcinol and salicylic acid of Merck are also irreverent. First, as discussed above, Luo teaches compositions comprising ethanol as hair growth compositions. Secondly, Merck teaches resorcinol as a composition comprising Castor oil and Alcohol, for the treatment of alopecia on fur bearing mammals, such as dogs; and is therefore relevant, pertinent, and makes the instantly claimed invention obvious. Therefore, applicants arguments are not found convincing and the rejection has been MAINTAINED.

Applicant's arguments filed February 6, 2003, Paper No. 12, to the rejection of claims 15-25 under 35 U.S.C. 103(a) as being unpatentable over The Merck Veterinary Manual, A Handbook of Diagnosis and Therapy for the Veterinarian (Merck) and further in view of Eggers et al., 4,849,455have been fully considered. However, they have not been found convincing; therefore, the said rejection has been MAINTAINED.

Applicant argues that resorcinol and salicylic acid have nothing to do with alcohols and Eggers et al is directed to virucides and that the treatment of

viruses has nothing to do with resorcinol. However, applicant acknowledges that Merck teaches treating alopecia. As discussed above, Merck is relied upon for its treatment of alopecia. Merck teaches acquired alopecia is due to a variety of diseases, particularly those causing febrile reactions and epithelial destruction and teaches that resorcinol (Rx 427) should be used to treat alopecia. Merck then teaches that Rx 427 is comprised of Castor oil and alcohol. The Eggers et al reference was relied upon for its teaching of the specific alcohols claimed as well as combining said alcohols with castor oil, which has the desired effect of improving skin compatibility when alcohols are applied to the skin.

Thus, Merck teaches castor oil and alcohols for the treatment of alopecia. Eggers et al teach the combination of alcohols (e.g. methanol and ethanol) with glycerol and castor oil as improving skin compatibility.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the alopecia treating composition of Merck by adding the specific alcohols methanol and ethanol as taught by Eggers because of the expectation of obtaining a skin treatment composition comprising methanol and ethanol that would have virucidal as well as alopecia treating properties.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Luo, H1480

Luo teaches methods of using dyphyllin, a compound having an alcohol group, as a promoter of hair growth. The reference teaches the topical application of dyphlline to mammals for regulating hair growth in a mammal, including domestic animals, such as cats and dogs that are suffering from hair loss.

Therefore, the reference teaches methods of applying alcohol to the skin of dogs and cats, to treat alopecia. See: col. 1, lines 5-24, line 62-68; col. 2, line 1 – col. 3, line 32; col. 8, lines 7-21, claims 1 and 3; and abstract.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-17 and 20-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luo, H1480 and further in view of The Merck Veterinary Manual, A Handbook of Diagnosis and Therapy for the Veterinarian (Merck).

Luo teaches methods of using dyphylline, a compound having an alcohol group, as a promoter of hair growth. The reference teaches the topical application of dyphylline to mammals for regulating hair growth in a mammal, including domestic animals, such as cats and dogs that are suffering from hair loss.

Therefore, the reference teaches methods of applying alcohol to the skin of dogs and cats, to treat alopecia. See: col. 1, lines 5-24, line 62-68; col. 2, line 1 – col. 3, line 32; col. 8, lines 7-21, claims 1 and 3; and abstract.

However, the reference lacks the method step of clipping the hair or removing the stratum corneum as claimed instantly in claims 17, 20, 22, and 24.

Merck teaches treating local alopecia with a resorcinol composition, which comprises of castor oil and alcohol. The reference teaches application of the composition to the affected skin and massaging the composition into the skin. Merck teaches that in cases of alopecia not arising from the endocrine system, removal of the diseased glands may be helpful. Moreover, the Merck reference teaches that particular attention should be given to skin cleanliness and that the extent of recovery depends on the amount of damage to the hair follicles. See: pages 915-916 and 1520.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the methods of topically treating hair loss as taught by Luo, by clipping the hair of the dog or cat and removing the diseased glands because of the expectation of obtaining a method of regulating hair growth by first removing diseased glands and then applying the composition to a clean skin surface, which would allow easier permeability of the hair growth composition.

Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over The Merck Veterinary Manual, A Handbook of Diagnosis and Therapy for the Veterinarian (Merck) as applied to claims 15-17 and 20-22, and 24 above, and further in view of Eggers et al., 4,849,455.

Merck teaches treating local alopecia with a resorcinol composition, which comprises of castor oil and alcohol. The reference teaches application of the

composition to the affected skin and massaging the composition into the skin. Merck teaches that in cases of alopecia not arising from the endocrine system, removal of the diseased glands may be helpful. See: pages 915-916 and 1520.

Although the primary reference teaches alcohol as the major ingredient of a composition to treat local alopecia, by topical application of said composition, the reference does not specifically teach that alopecia has occurred after the hair has been clipped, as claimed instantly in claim 17 and 22, the specific alcohols of instant claims 18-20, 23, or 25, the treatment of cats as claimed instantly in claim 21, or removing the stratum corneum of the skin as claimed instantly in claim 24.

Eggers teaches a virucidal agent against naked vires containing at least 70% methanol, and /or ethanol and from 1-10% glycerol and optionally up to 5% castor oil for improving the skin. The secondary reference teaches that the addition of glycerol to methanol and ethanol does not adversely affect the efficacy of these alcohols and that castor oil does not deteriorate the activity against naked viruses, while the castor oil does improve the skin compatibility. See: col. 1, line 10 – col. 4, line 2.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the alopecia treating composition of Merck by adding the specific alcohols methanol and ethanol as taught by Eggers because of the expectation of obtaining a skin treatment composition comprising methanol and ethanol that would have virucidal as well as alopecia treating properties.

It would have also been obvious to remove hair and the stratum corneum because as taught by Merck, the removal of diseased glands may be helpful. Moreover the Merck reference teaches particular attention should be given to skin cleanliness and that the extent of recovery depends on the amount of damage to the hair follicles. Merck lacks the specific teaching of treating cats, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the alopecia treating formulation of Merck to other fur/hair bearing animals because of the reasonable expectation that a composition useful for the treatment of alopecia on dogs would also be useful for the treatment of alopecia on other fur/hair bearing animals such as cats.

Moreover, the use of isopropanol in conjunction with ethanol and methanol would have been obvious to one having ordinary skill in the art at the time the invention was made because isopropanol is a commonly used, topically applied germicide, which is cheap, easy to use and would be expected to add germicidal properties to a virucidal, alopecia treating composition useful for fur/hair bearing animals.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614

June 12, 2003